MAR 1 5 2001

K010523

Vital Answers For Better Health...NOW™

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: _____

The summary was prepared on February 2, 2001

Submitter:

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Trade Name:

Binax NOW® *Streptococcus pneumoniae* Urinary Antigen Test

Common Name:

Strep pneumo ICT

Classification Name:

Streptococcus spp. serological reagents (per 21 CFR 8660.3740)

Unmodified Device (predicate):

Binax NOW® *Streptococcus pneumoniae* Urinary Antigen Test, 510(k) number K991726.

Device Description:

The Binax NOW® *Streptococcus pneumoniae* Urinary Antigen Test is an immunochromatographic membrane assay used to detect *Streptococcus pneumoniae (S. pneumoniae)* antigen in human urine. A test strip, containing gold-conjugated and immobilized anti-*S. pneumoniae* antibodies, and a swab well are mounted on opposite sides of a cardboard, book-shaped hinged test device. A swab is dipped into the urine to be tested and then inserted into the swab well. A single reagent is added to the swab well from a dropper bottle before closing the test device. Pneumococcal urinary antigen captured by immobilized anti-*S. pneumoniae* antibody reacts to bind anti-*S. pneumoniae* conjugated antibody, forming the Sample Line. Immobilized control antibody captures anti-species conjugate, forming the Control Line. There are no transferring steps, the sample is contained, and results are available within 15 minutes.

510(k) SUMMARY (Continued)

Intended Use:

The Binax NOW® *Streptococcus pneumoniae* Urinary Antigen Test is an *in vitro* rapid immunochromatographic (ICT) assay for the detection of *Streptococcus pneumoniae* (*S. pneumoniae*) antigen in urine specimens from patients with symptoms of pneumonia. It is intended to aid in the presumptive diagnosis of pneumococcal pneumonia in conjunction with culture and other methods.

Technological Characteristics:

The modified and cleared Binax NOW® *Streptococcus pneumoniae* Urinary Antigen tests share the same technological characteristic and antigen detection reagents. Assay procedure, intended use and product claims are unchanged for the modified device.

Performance Summary:

The modified and cleared Binax NOW® *Streptococcus pneumoniae* Urinary Antigen Tests are substantially equivalent, as verified using characterized frozen urine specimens.

Analytic Sensitivity (LOD Testing)

The limit of detection (LOD) for the 510(k) cleared NOW® test, as reported in product labeling, was identified as 1:250 for a known positive patient urine. In order to verify that the modified test continues to detect this LOD level, a 1:250 dilution of this same positive patient urine was tested, producing positive results in the modified test 100% of the time. These results indicate that the LOD for the modified test is at least equivalent to that of the cleared test.

Analytic Specificity (Cross-Reactivity)

Given that the modifications to the device do NOT impact the detection portion of the assay, a limited cross-reactant panel of 51 organisms was tested. The cross-reactant panel included organisms associated with pneumonia as well as those likely to be found in the urogenital tract as normal flora or as a result of urinary tract infection. As in the 510-cleared test, none of the organisms, grown in culture and diluted to 1 x 10^6 CFU/ml, tested positive in the modified test.

Clinical Sensitivity and Specificity

The modified NOW® test was evaluated in a limited retrospective clinical study. Archived urine specimens collected from confirmed blood culture positive and blood culture negative patients were evaluated in both the modified and 510(k)-cleared tests. There was 97% agreement between modified and unmodified Binax NOW® tests. Results, with 95% confidence intervals, are listed below.

510(k) SUMMARY (Continued)

		NOW® +	NOW® -	
Modified Test	+	23	1	
	-	1	45	
		Sensitivity: 96%		80-99%
		Specificity: 98%		89-100%
		Accuracy: 97%		90-99%

Interfering Substances

The modified NOW® test, like the 510(k)-cleared test, was found not to cross-react with potentially interfering substances present in urine. Nineteen (19) urine specimens with elevated levels of white blood cells, red blood cells, protein, glucose, or urines with high turbidity were assayed in the modified NOW® test. All specimens tested negative.

Preliminary Stability

Preliminary stability studies of the modified NOW® test are ongoing. Test results are consistent with the Binax 510(k) cleared test. A minimum shelf life of one year is anticipated.

Signed J. Georges Nitis Ph.D Date 2/21/01

J. Georges Nitis, Ph.D., MBA
Director, Regulatory and Clinical Affairs

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR 1 5 2001

Ms. Pamela Angell
Program Planning and Implementation
Binax, Inc.
217 Read Street
Portland, ME 04103

Re: K010523
Trade Name: Binax Now® Streptococcus Pneumoniae Urinary Antigen Test
Regulatory Class: II
Product Code: GTZ
Dated: February 21, 2001
Received: February 22, 2001

Dear Ms. Angell:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE ENCLOSURE

510(k) Number (if known): K010523

Device Name: Binax NOW® *Streptococcus pneumoniae* Urinary Antigen Test

Indications for Use:

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PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Woody Dubois
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K010523

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)